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RICHARD WOLF
Medical Instruments Corporation

OCT 5 - 2005

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12.0 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: **May 4, 2005**
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:

Trade name: Flexible Video-Endoscope	Model number: 7308.061, 7308.066
Common name: Flexible Video Cystoscope / Choledochoscope	Classification name: Cystoscope / Nephroscope /Choledochoscope

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K980401	1 Flexible Fiberscopes and Accessories	1 Richard Wolf
2 K 021074	2 Cysto-Videoscope VISERA CYF-V, CYF-VA	2 Olympus
3 K30960	3 Digital Flexible Cysto-Videoscope DCN	3 ACMI
4 K023659	4 1 CCD Endocam 5520 System	4 Richard Wolf
5 K983279	5 1 CCD Multi Endocam 5502 with Electronic CCD Endoscope 4934.551	5 Richard Wolf

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RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

1.0 Description

The submitted flexible video cystoscopes / choledochoscopes are a modification of the Richard Wolf flexible fiber-cystoscopes. The submitted flexible video cystoscopes have a CCD video image sensor for generating a video image with a camera controller instead of an image fiber light guide. The submitted video cystoscopes connect to the Richard Wolf camera system 5520.

2.0 Intended Use

The Flexible Video Cystoscope is used for visualizing body cavities and organs via natural and surgically generated passages. For examination, diagnosis and/or therapy in conjunction with endoscopic accessories/auxiliary instruments through the scope's working channel. The scope is used in the medical disciplines of Urology (urogential tract, cystoscopy, nephroscopy) and Surgery (choledochoscopy).

3.0 Technological Characteristics

The videoscopes have similar dimensions, working channels and design as the Richard Wolf flexible fiber-cystoscopes. Both cystoscopes are designed with a control lever for locking the tip in any angled position. Two different control directions are available, i.e. the endoscope is deflected either upward or downward upon activating the control lever proximally or distally. The tips are angled approximately 45^0 and angled. This makes the insertion into the urethra easier and more comfortable for male patients. The adapter with instrument port, irrigation and drain stopcocks and optional biopsy valve is removable. The new style ergonomic handle is equipped with two remote control buttons that control the camera function.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as existing devices and the new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf, Olympus and ACMI.

5.0 Performance Data

The flexible videoscopes 7301.061 / 7301.066 are designed to meet the standards IEC601-1/ UL2601-1 and IEC601-1-2.

6.0 Clinical Tests

No special clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

By: Robert L. Casarsa

Robert L. Casarsa
Quality Assurance Manager

Date: May 4, 2005

OCT 5 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporations
353 Corporate Woods Parkway
VERNON HILLS IL 60061-3110

Re: K051176
Trade/Device Name: Flexible Video Cystoscope / Choledochoscope
(Models 7308.061 and 7308.066)
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: FBN and FAJ
Dated: September 7, 2005
Received: September 9, 2005

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 Indications for Use

510(k) Number: K051176

Device Name: Flexible Video Cystoscope / Choledochoscope

Indications For Use: The Flexible Video Cystoscope is used for visualizing body cavities and organs via natural passages. For examination, diagnosis and/or therapy in conjunction with endoscopic accessories/ auxiliary instruments through the scope's working channel. The scope is used in the medical disciplines of

- Urology (urogenital tract, cystoscopy, nephroscopy)
- Surgery (choledochoscopy)

Prescription Use ✓ AND/OR Over-The Counter _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051176